

**IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
RICHMOND DIVISION**

**Lisa Sykes and Seth Sykes, Individually
and as Parents and Natural Guardians of
Wesley Alexander Sykes, a minor child,**

Plaintiffs,

V.

Bayer Corporation, aka Bayer Corporation, Inc., et al.

Defendants.

CIVIL ACTION NUMBER: 3:07CV660

ANSWER OF DEFENDANT BAYER CORPORATION

Bayer Corporation (“Bayer Corporation”), incorrectly named in the Amended Complaint as Bayer Corporation, aka Bayer Corporation, Inc., Bayer Corporation, Inc., Bayer Biological Products, Bayer HealthCare Corporation, Inc., Bayer Pharmaceuticals Corporation, and Bayer Pharmaceuticals Corporation, Inc., Individually and as Successor-In-Interest to Miles, Inc., in response to Plaintiffs’ Amended Complaint, answers as follows:

SUMMARY OF ALLEGATIONS

1. Bayer Corporation admits only that it or its predecessor companies engaged in the sale and distribution of HypRho-D® until late 1995, early 1996. HypRho-D® was sold through distributors and not to the general public. Except as expressly admitted, this paragraph is denied.

2. Bayer Corporation admits: that HypRho-D® is the provision of an immune globulin service for Rh-negative pregnant women which contained thimerosal, as a preservative required by the FDA at the time that the FDA licensed HypRho-D in the postpartum and antenatal indications; that thimerosal contains approximately 50% ethyl mercury, which is not toxic to the mother or unborn child at this dose; that HypRho-D® was indicated only for

intramuscular injection; that HypRho-D® containing thimerosal was discontinued in 1995 or 1996. Bayer Corporation denies the dose of thimerosal in HypRho-D could have caused toxicity to a mother receiving the shot, or to her unborn child. Except as expressly admitted, this paragraph is denied.

3. Bayer Corporation denies the allegations of this paragraph.

PARTIES AND JURISDICTION

4. Bayer Corporation is without knowledge or information sufficient to form a belief as to the truth of such allegations, and accordingly they are denied.

5. Bayer Corporation admits only that it is an Indiana Corporation and that it or its predecessor companies designed, manufactured, tested, labeled, promoted, marketed, distributed, sold and warranted HypRho-D®. Except as expressly admitted, this paragraph is denied.

6. Bayer Corporation admits only that Cutter Laboratories, Inc. (“Cutter”) originally designed, developed, manufactured and sold HypRho-D®, that Bayer AG acquired Cutter in 1974, that Cutter merged into Miles Laboratories, Inc. in 1983, that Miles Laboratories, Inc. merged into Miles Inc. in 1987 and that Miles Inc. changed its name to Bayer Corporation in 1995. Except as expressly admitted, this paragraph is denied.

7. Denied.

8. Denied.

9. Denied.

FACTUAL ALLEGATIONS

10. Bayer Corporation admits that ethyl mercury at a dose many times higher than that in a shot of HypRho-D® can be toxic. Except as expressly admitted herein, this paragraph is denied.

11. Bayer Corporation admits that ethyl mercury at a dose many times higher than that in a shot of HypRho-D® can be toxic. Except as expressly admitted herein, this paragraph is denied.

12. Bayer Corporation admits there are reported cases of exposures to mercury which have caused injuries. Except as expressly admitted herein, this paragraph is denied.

13. Bayer Corporation admits that thimerosal contains approximately 50 % ethyl mercury by weight, and that thimerosal was widely used by many regulated and over the counter medications for approximately 60 years. Except as expressly admitted, this paragraph is denied.

14. Bayer Corporation admits: that it used HypRho-D® as a thimerosal as approved by the FDA in Bayer Corporation's license; that HypRho-D® was provided for administration to pregnant women who were Rhesus negative at approximately 28 weeks gestation, in accordance with Bayer's FDA-approved label. Except as expressly admitted, this paragraph is denied.

15. Denied.

16. Denied.

17. Denied.

18. Denied.

19. Bayer Corporation admits that doses of ethyl mercury many times higher than that in HypRho-D® can cause toxicity. Except as expressly admitted herein, this paragraph is denied.

20. Bayer Corporation admits it provided HypRho-D® containing thimerosal for administration to Rhesus-negative pregnant women. Except as expressly admitted, this paragraph is denied.

21. Denied.

22. Bayer Corporation admits only that it discontinued the use of thimerosal in HypRho-D® in 1996. Except as expressly admitted, this paragraph is denied.

23. Denied.

24. Denied.

25. Denied.

26. Bayer Corporation admits HypRho-D® was intended for Rhesus-negative pregnant women. Except as expressly admitted, this paragraph is denied.

27. Denied.

28. Bayer Corporation admits that doses of ethyl mercury many times higher than that in HypRho-D® can cause toxicity. Except as expressly admitted herein, this paragraph is denied.

29. Denied.

30. Bayer Corporation denies there is any evidence Lisa Sykes received a shot of HypRho-D®, and therefore denies the remainder of the allegations of this paragraph.

COUNT ONE: NEGLIGENCE (DESIGN DEFECT)

31. Bayer Corporation incorporates by reference the earlier paragraphs of this Answer.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

COUNT TWO: BREACH OF WARRANTIES

36. Bayer Corporation incorporates by reference the earlier paragraphs of this Answer.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

Bayer Corporation denies liability for any injury alleged in the Amended Complaint and denies that Plaintiffs are entitled to the relief requested in the Amended Complaint. Bayer Corporation further denies any allegations that its conduct gives rise to punitive damages.

Wherever Plaintiffs have incorporated by reference prior allegations in the Amended Complaint, Bayer Corporation incorporates by reference its responses to such allegations.

Bayer Corporation denies each and every allegation in the Amended Complaint that relates to or is directed to Bayer Corporation unless such allegations are expressly responded to in this Answer.

ADDITIONAL DEFENSES

Discovery and investigation may reveal that one or more of the following additional defenses should be available to Bayer Corporation in this matter. Bayer Corporation accordingly reserves the right to assert these separate and additional defenses. Upon completion of discovery, if the facts warrant, Bayer Corporation may withdraw any of these additional defenses as may be appropriate. Bayer Corporation further reserves the right to amend its answer and defenses and to assert additional defenses and other claims, as discovery proceeds. Further answering, and by way of additional defense, Bayer Corporation states as follows:

Defense No. 1. Plaintiffs' Amended Complaint and each and every count therein fail to state a cause of action or claim upon which relief can be granted against Bayer Corporation.

Defense No. 2. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitation and/or statutes of repose.

Defense No. 3. Plaintiffs' claims are barred, in whole or in part, by laches, waiver, or estoppel.

Defense No. 4. Plaintiffs' Amended Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

Defense No. 5. To the extent applicable to the facts and circumstances of this case, Plaintiffs are not the real parties in interest and lack capacity or standing to bring the claims asserted in the Amended Complaint.

Defense No. 6. The alleged damages and injuries, if any, were the result of unavoidable circumstances that could not have been prevented by any person or entity, including Bayer Corporation.

Defense No. 7. Plaintiffs have not suffered any actual injury, loss, or damages because of the alleged use of HypRho-D®.

Defense No. 8. The injuries and damages sustained by Plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and no act or omission on the part of Bayer Corporation was a proximate or competent producing cause of such alleged injuries or damages.

Defense No. 9. The injuries sustained by Plaintiffs, if any, were caused, in whole or in part, by pre-existing or subsequent physical, medical, and/or physiological conditions, for which Bayer Corporation has no legal responsibility.

Defense No. 10. The acts and omissions of Plaintiffs or other persons or entities, over whom Bayer Corporation had no supervision or control and for whose actions and omissions Bayer

Corporation has no legal responsibility, caused or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrines of comparative or contributory negligence. Plaintiffs' recovery, if any, therefore is barred or should be reduced and/or apportioned in accordance with applicable law.

Defense No. 11. Plaintiffs' claims are barred pursuant to the Restatement (Second) of Torts, section 402A, comment k.

Defense No. 12. Bayer Corporation did not sell or distribute HypRho-D® to Plaintiffs and Plaintiffs did not receive or rely on any representations or warranties as alleged in the Amended Complaint. Plaintiffs' claims for breach of warranty are barred by lack of privity between Plaintiffs on one hand and Bayer Corporation on the other.

Defense No. 13. Plaintiffs' claims are barred because HypRho-D® was neither defective nor unreasonably dangerous in its design, manufacture, or marketing and was reasonably safe and reasonably fit for its intended use, thereby barring Plaintiffs' recovery.

Defense No. 14. Plaintiffs' claims are barred, in whole or in part, because HypRho-D® does not violate any prevailing safety standard or deviate from reasonable consumer expectations.

Defense No. 15. Plaintiffs' claims are barred by the learned intermediary doctrine.

Defense No. 16. Plaintiffs did not detrimentally rely on any labeling, warnings, or information concerning HypRho-D®.

Defense No. 17. Plaintiffs' claims for breach of warranty, express and implied, are barred because Plaintiffs failed to give timely notice of any alleged breach of warranty.

Defense No. 18. Plaintiffs' claims for breach of warranty, express and implied, are barred by applicable law.

Defense No. 19. Plaintiffs' Amended Complaint fails to state a claim upon which relief can be

granted in that the methods, standards, and techniques utilized with respect to the design, manufacture, testing, distribution, marketing, and sale of HypRho-D®, including but not limited to adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art. HypRho-D®, including its labeling approved by the United States Food and Drug Administration, complied with the state of scientific and medical knowledge available at the time of its design, testing, manufacture, distribution, marketing, and sale. Plaintiffs' recovery accordingly is barred.

Defense No. 20. HypRho-D® complied with the applicable product safety regulations promulgated by the United States Food and Drug Administration. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, distribution, marketing, and sale of HypRho-D®, and that it was neither defective nor unreasonably dangerous. Plaintiffs' recovery accordingly is barred.

Defense No. 21. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of HypRho-D®. Plaintiffs' recovery accordingly is barred.

Defense No. 22. Any alleged exposure to HypRho-D®, and any alleged conduct of Bayer Corporation, was insufficient to be a substantial contributing cause to the injuries and damages alleged.

Defense No. 23. Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution by reason of the federal government's regulation of the manufacturing, testing, marketing, sale, and labeling of prescription drugs.

Defense No. 24. Any claims by Plaintiffs relating to alleged communications with

governmental regulatory agencies are barred in whole or in part under applicable law, including the First and Fourteenth Amendment rights to petition the government.

Defense No. 25. Plaintiffs' claims are barred, in whole or in part, by the failure of Plaintiffs to mitigate the damages alleged.

Defense No. 26. To the extent Plaintiffs seek recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Amended Complaint, such benefits are not recoverable in this action.

Defense No. 27. To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Amended Complaint, the liability of Bayer Corporation, if any, should be reduced.

Defense No. 28. Upon information and belief, each item of economic loss alleged in the Amended Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, by collateral sources.

Defense No. 29. Plaintiffs' Amended Complaint fails to state a claim upon which relief can be granted as to costs and disbursements or interest.

Defense No. 30. This Court's Opinion of February 12, 2008 states that it would be futile to add a claim for punitive damages. Thus, Plaintiffs' are barred from asserting any punitive damages claims.

Defense No. 31. Plaintiffs' Amended Complaint fails to state a claim against Bayer Corporation upon which relief can be granted for punitive or exemplary damages.

Defense No. 32. Bayer Corporation pleads the general issue and denies that it is liable or responsible for any alleged damages to Plaintiffs.

Defense No. 33. Bayer Corporation denies any conduct for which punitive or exemplary

damages could or should be awarded and denies that Plaintiffs have produced evidence sufficient to support or sustain the imposition of punitive damages against Bayer Corporation pursuant to the applicable standards of proof.

Defense No. 34. Permitting recovery of punitive or exemplary damages in this case would be unconstitutionally vague or overbroad, would violate Bayer Corporation's constitutional rights, as secured by the Fifth, Seventh, Eighth, Tenth and Fourteenth Amendments to the United States Constitution, federal common law, and the Constitution of Virginia, Article 1, Sections 8, 9, and 11, and would contravene the prohibition of excessive fines and other provisions of the United States Constitution and any other applicable state constitution.

Defense No. 35. Plaintiffs cannot recover punitive or exemplary damages against Bayer Corporation because such an award, which is penal in nature, would violate Bayer Corporation's rights under the United States Constitution and any applicable state constitution, unless Bayer Corporation is afforded the same procedural safeguards as are criminal defendants.

Defense No. 36. Any imposition of punitive or exemplary damages in this case against Bayer Corporation would contravene the Commerce Clause of the United States Constitution, in that such an award would constitute an undue and unreasonable burden on interstate commerce.

Defense No. 37. With respect to Plaintiffs' demand for punitive or exemplary damages, Bayer Corporation incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under applicable state law.

Defense No. 38. No act or omission of Bayer Corporation was intentional, fraudulent, malicious, willful, wanton, reckless, in any way morally culpable, or made with conscious, malicious, or intentional disregard for the health and well-being of Plaintiffs or others. Bayer

Corporation asserts all statutory or judicial protections from punitive or exemplary damages that are available under applicable law, and any award of punitive or exemplary damages is barred.

Defense No. 39. Plaintiffs' claim for punitive or exemplary damages cannot be sustained because, in all respects pertinent to this action, Bayer Corporation complied with applicable industry standards and did not engage in a deliberate course of conduct which knowingly endangered those using HypRho-D®.

Defense No. 40. Plaintiffs' claim for punitive damages cannot be sustained to the extent that, prior to the entry of any judgment or award in this case, an award of punitive or exemplary damages has been recovered from Bayer Corporation in a court of this state relating to HypRho-D®.

Defense No. 41. To the extent Plaintiffs seek an award for punitive damages for Negligent Design, Plaintiffs have failed to state a claim upon which relief may be granted. *See Ford Motor Co. v. Bartholomew*, 224 Va. 421, 437, 297 S.E.2d, 684 (1982) ("simple negligence in design and negligent failure to correct or to warn" held insufficient to support award of punitive damages).

Defense No. 42. To the extent Plaintiffs seeks an award for punitive damages for Breach of Warranties, Plaintiffs have failed to state a claim upon which relief may be granted. *See Bettius & Sanderson, P.C. v. Nat'l Union Fire Ins. Co.*, 839 F.2d 1009, 1015 (4th Cir. 1998) (finding that under Virginia law mere breach of a duty imposed by contract is insufficient for imposition of punitive damages).

Defense No. 43. Plaintiffs have failed to allege sufficiently egregious conduct to warrant imposition of punitive damages against Bayer Corporation. *See Bowers v. Westvaco Corp.*, 244

Va. 139, 150 419 S.E.2d 661, 668 (Va. 1992) (stating punitive damages only available for the most egregious conduct).

Defense No. 44. Plaintiffs' claim for punitive damages is limited to a maximum of \$350,000 for all claims asserted against Bayer Corporation. *See* Va. Code §8.01-38.1; *Al-Abood ex rel. Albood v. El-Shamari*, 217 F.3d 225, 237 (4th Cir. 2000) (interpreting Virginia as applying cap to punitive damages to action as a whole).

Defense No. 45. Plaintiffs' claim for punitive damages is barred because HypRho-D® and its labeling was subject to and received pre-market approval by the FDA.

Defense No. 46. Plaintiffs' Amended Complaint seeks damages in excess of those permitted by law. Bayer Corporation asserts any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

Defense No. 47. Plaintiffs' Amended Complaint fails to state a claim on which relief can be granted for joint and several liability.

Defense No. 48. Bayer Corporation asserts all allowable defenses under the laws of Virginia and any other applicable state law.

Defense No. 49. Bayer Corporation adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Bayer Corporation's defenses pleaded in this Answer.

WHEREFORE, Bayer Corporation denies any and all liability to Plaintiffs, and respectfully requests that Plaintiffs' claims against it be dismissed with prejudice and that Bayer Corporation be awarded such general, further relief as justice may require.

DATED: March 17, 2008

BAYER CORPORATION

/s/ William P. Childress

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CERTIFICATE OF SERVICE

I herby certify that on the 17 day of March, 2008, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send notification of such filing to the following:

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